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PRESS RELEASE
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New Lassa Vaccine Trial in Nigeria

The International AIDS Vaccine Initiative (IAVI) was awarded €22.8 million by the European & Developing Countries Clinical Trials Partnership and the Coalition for Epidemic Preparedness Innovations (CEPI) to conduct a Phase IIb clinical trial of IAVI's Lassa fever vaccine candidate among adults and children in Liberia, Nigeria, and Sierra Leone. The vaccine candidate uses a recombinant vesicular stomatitis virus vector, which is now registered for use in eight African countries.

This joint award supports an international collaboration across Africa, Europe, and North America, called the "Lassa Fever Vaccine Efficacy and Prevention for West Africa" (LEAP4WA), which will also strengthen the research capacity of investigational sites where Lassa fever outbreaks and disease occur frequently. The LEAP4WA consortium consists of the following members: IAVI Inc., U.S.; IAVI Stichting, Netherlands; Tulane University School of Public Health and Tropical Medicine, U.S.; Ministry of Health and Sanitation/Kenema Government Hospital in Sierra Leone; Imperial College of Science Technology and Medicine, U.K.; University of Liberia, Liberia; Epicentre, France; and Henry M. Jackson Foundation Medical Research International Ltd/Gte (HJFMRI), Nigeria. In Nigeria, HJFMRI will conduct the study at its Clinical Research Center (CRC) supported by the Walter Reed Army Institute of Research.

Other supported WRAIR Lassa projects being implemented at the CRC and other sites across Nigeria include a Lassa incidence study in collaboration with the African Center of Excellence for Genomics of Infectious Diseases (ACEGID), a Lassa seroprevalence study, and a potential opportunity for a CEPI-funded Phase IIa Lassa vaccine study through a WRAIR/IAVI collaboration.

When infected with Lassa fever virus, patients exhibit a high fever accompanied by bleeding, sore throat, vomiting, and body pains. The zoonotic virus, which rapidly spreads through bodily fluids, is transmitted to man by an infected multi-mammate rat, (*mastomys natalensis*). The illness was first reported in the Lassa community in Borno State, Nigeria, when two missionary nurses died from an unusual febrile illness. Since then, outbreaks continue to be reported in Nigeria and the disease, which is gradually becoming endemic in many parts of West Africa is now being transported to overseas country like the US and UK.

Despite these outbreaks, there is yet no Lassa fever vaccine. An estimated 300,000 to 500,000 Lassa fever cases are diagnosed annually, resulting in approximately 5,000 deaths. The World Health Organization has identified Lassa fever as one of the top emerging pathogens likely to

cause severe outbreaks in the near future. In 2018, the Nigeria Centre for Disease Control (NCDC) reported the largest ever number of cases in Nigeria, with over 600 confirmed cases and over 170 deaths. As of May 2021, 14 states have recorded at least one confirmed case and over 2000 suspected cases this year, with the majority of cases emanating from Edo and Ondo states.

CRC was established in 2014, initially supporting Phase II Ebola vaccine trials funded by Glaxo Smith Kline and Janssen. Since that time, its rapidly expanding research efforts have covered a broad range of infectious diseases. Of note, current research also includes two COVID-19 studies. Site preparations are ongoing for an imminent Phase III SARS-CoV-2 candidate vaccine trial sponsored by Sanofi Pasteur. Under a collaborative grant application between HJFMRI and ACEGID, the CRC was selected for an Africa Centre for Disease Control grant to potentially conduct a study entitled "Assessing the Effect of SARS-CoV-2 Variants on Vaccine-induced and Naturally-acquired Immune Responses in Nigeria" (SARS-CoVAN Project).

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